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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,923	04/19/2004	Shailaja Kasibhatla	1735.0870001/RWE/ALS	1333

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EXAMINER

FETTEROLF, BRANDON J

ART. UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,923

Applicant(s)

KASIBHATLA ET AL

Examiner

Brandon J. Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, as specifically drawn to a method of treating, preventing, ameliorating a disease responsive to induction of the caspase cascade in an animal, comprising administering to an animal a compound which specifically binds to a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP), wherein said compound induces activation of the caspase cascade, classified in class 424, subclass 130.1.
- II. Claims 10-20, as specifically drawn to a method of identifying potentially therapeutic anticancer compounds comprising: (a) contacting a Tail Interacting Protein Related Apoptosis Inducing Protein (TIPRAIP) with one or more test compounds; and (b) monitoring whether said one or more test compounds binds to said TIPRAIP, classified in class 435, subclass 4.
- III. Claim 21, as specifically drawn to a method of identifying potentially therapeutic anticancer compounds comprising: (a) contacting said compound with an antibody to 3-(4-azidophenyl)-5-(3-chloro-thiophen-2-yl)-[1,2,4]-oxadiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxadiazole; and (b) determining whether said compound binds to said antibody, classified in class 435, subclass 4.
- IV. Claim 22, as specifically drawn to a method of prognosing the efficacy of an anti-cancer TIPRAIP binding composition in a cancer patient comprising: (a) taking a fluid or tissue sample from an individual manifesting a cancer; (b) quantifying the total mRNA encoding TIPRAIP; (c) calculating a ratio comprising the quantity of said mRNA to average quantity of said mRNA in a fluid or tissue not manifesting said cancer; wherein a ratio greater than 1 indicates that said anti-cancer TIPRAIP binding composition is efficacious, classified in class 435, subclass 6.

- V. Claim 23, as specifically drawn to a method of prognosing the efficacy of an anti-cancer TIPRAIP binding composition in a cancer patient comprising: (a) taking a fluid or tissue sample from an individual manifesting a cancer; (b) quantifying the TIPRAID present in said sample; (c) calculating the ratio comprising the quantity of said TIPRAIP to the average quantity of said TIPRAIP in a fluid or tissue not manifesting said cancer; wherein a ratio greater than 1 indicates that said anti-cancer TIPRAIP binding composition is efficacious, classified in class 435, subclass 7.2.
- VI. Claim 24, as specifically drawn to a complex comprising: a TIPRAIP and a TIPRAIP binding compound, classified in class 530, subclass 350.
- VII. Claims 25-28, as specifically drawn to a detectably labeled and or composition comprising 3-(4-azidophenyl)-5-(3-chloro-thiophen-2-yl)-[1,2,4]-oxadiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxadiazole, classified in class 544, subclass 138.
- VIII. Claim 29, as specifically drawn to a method of treating, preventing or ameliorating a disease responsive to induction of the caspase cascade in an animal, comprising administering to said animal a compound which i) increases the level of cellular mRNA encoding transforming growth factor beta, cyclin-dependent kinase inhibitor 1A, insulin-like growth factor 2 receptor, or insulin-like growth factor binding protein 3; or ii) decreases the level of cellular mRNA encoding cyclin D1, classified in class 514, subclass 1.
- IX. Claim 30, as specifically drawn to a method of identifying potentially therapeutic anticancer compounds comprising: (a) contacting cells with one or more test compounds; and (b) monitoring i) cellular increases in mRNA encoding transforming growth factor beta, cyclin-dependent kinase inhibitor 1A, insulin-like growth factor 2 receptor, or insulin-like growth factor binding protein 3; or ii) cellular decreases in the level of mRNA encoding cyclin D1, classified in class 435, subclass 4.

- X. Claim 31, as specifically drawn to a method of treating, preventing or ameliorating a disease responsive to induction of the caspase cascade in an animal, comprising administering to said animal a compound which interferes with or prevents the binding of TIP-47 to insulin-like growth factor 2 receptor, classified in class 514, subclass 1.
- XI. Claim 32, as specifically drawn to a method of identifying potentially therapeutic anticancer compounds comprising monitoring whether one or more test compounds interfere with or prevent the binding of TIP-47 to insulin-like growth factor 2 receptor, classified in class 435, subclass 4.

Note:

This application contains claims, 29 and 30, directed to patentably distinct inventions: each of the specifically claimed mRNA's lack unity of invention because the amino acid sequences have no substantial structural similarities although they have a common utility, i.e. identifying a potentially therapeutic compound. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

In the instant case, there are approximately eight different databases that accompany the results of a search of one discrete nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of five different nucleotide sequences, and different nucleotide segments in the databases would require extensive searching and review.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed mRNA for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I, Group VIII and Group X are directed to related methods of treating, preventing or ameliorating a disease responsive to the induction of the caspase cascade in an animal. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the related methods of treatment performs this function using structurally and functionally divergent material which demonstrates that each method has a different mode of operation. For example, the method of Group I utilizes a compound which specifically binds to a TIPRAIP protein, whereas the method of Group VIII utilizes a compound which increase or decreases the cellular level of a variety of mRNA's. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I, VIII and X are patentably distinct.

Furthermore, searching the inventions of Groups I, VIII and X together would impose a serious search burden. In the instant case, a search of the compounds, in either the patent databases or non-patent literature, which bind to a TIPRAIP polypeptide, decrease or increase the cellular expression of mRNA or prevents binding of TIP-47 to insulin-like growth factor 2 receptor are not coextensive because each of the compounds bind to structurally and functionally distinct molecules. As such, it would be burdensome to search the inventions of Groups I, VIII and X.

The inventions of Group II-III, IX and XI are directed to related methods of identifying potentially therapeutic anticancer compounds. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the related methods of identifying potentially anticancer compounds performs this function using structurally and functionally divergent material and method steps which demonstrates that each method has a different mode of operation. For example, the method of Group II comprises identifying compounds which bind to TIPRAIP, whereas the method of Group III comprises identifying compounds which bind to an antibody. Moreover, the method of Group IX identifies compounds which increase or decrease the levels of cellular mRNA, whereas the

invention of Group XI identifies compounds which interfere with or prevent the binding of TIP-47 to insulin-like growth factor receptor-2. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups II-III, IX and XI are patentably distinct.

Furthermore, searching the inventions of Groups II-III, IX and XI together would impose a serious search burden. In the instant case, a search of the compounds, in either the patent databases or non-patent literature, which bind to a TIPRAIP polypeptide, antibody, decrease or increase the cellular expression of mRNA or prevents binding of TIP-47 to insulin-like growth factor 2 receptor are not coextensive because each of the compounds bind to structurally and functionally distinct molecules. As such, it would be burdensome to search the inventions of Groups II-III, IX and XI.

The inventions of Group IV-V are directed to related methods of prognosing the efficacy of an anti-cancer TIRAIP binding composition in a cancer patient. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each of the related of prognosing the efficacy of an anti-cancer TIRAIP binding composition in a cancer patient performs this function using structurally and functionally divergent material and method steps which demonstrates that each method has a different mode of operation. For example, the method of Group IV comprises quantifying the total mRNA encoding TIPRAIP, whereas the method of Group V comprises quantifying the TIPRAID present in a sample. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups IV-V are patentably distinct.

Furthermore, searching the inventions of Groups IV-V together would impose a serious search burden. In the instant case, the distinct steps and products require separate and distinct searches. The inventions of Groups IV-V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV-V.

The inventions of Group VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the complex

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comprising TIPRAIP and a TIPRAIP binding compound (Group I) and the composition comprising 3-(4-azidophenyl)-5-(3-chloro-thiophen-2-yl)-[1,2,4]-oxadiazole or a substituted 3-aryl-5-aryl-[1,2,4]-oxadiazole (Group VII) are all structurally, chemically and/or functionally distinct compounds such that one invention could not be interchanged with the other. For these reasons the inventions of Groups VI-VII are patentably distinct.

The inventions of Groups VI-VII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups VI-VII. As such, each invention would require different searches and the consideration of different patentability issues.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species:

Claim 4, Group I, is generic to a plurality of disclosed patentably distinct species comprising the following cancer: Hodgkin's disease, non-Hodgkin's lymphoma, acute and chronic lymphocytic leukemia's, multiple myeloma, ... adrenal cortex carcinomas, skin cancer, or prostatic carcinomas which differ at least in morphologies and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER